

THE CLAIMS

We claim:

1. A dosage regimen for administering tramadol to a patient comprising administering: about 75 mg to about 125 mg of tramadol in a controlled release dosage
5 form once-a-day for about 4 to about 10 days; then about 175 mg to about 225 mg of tramadol in a controlled release dosage form once-a-day for about 4 to about 10 days; then about 275 mg to about 325 mg of tramadol in a controlled release dosage form once-a-day for at least 1 day and optionally thereafter.
2. The dosage regimen of claim 1 wherein the controlled release dosage forms
10 are each oral dosage forms.
3. The dosage regimen of claim 2 wherein the tramadol is present in each oral dosage form in a form selected from the group consisting of a free form of tramadol, a pharmaceutically acceptable salt of tramadol, a base form of tramadol, an optically active isomer of tramadol and a stereoisomer of tramadol.
- 15 4. The dosage regimen of claim 3 wherein the tramadol is present in each oral dosage form in the form of tramadol hydrochloride.
5. The dosage regimen of claim 4, wherein each oral dosage form provides *in vitro* release of tramadol hydrochloride for about 24 hours or longer.
6. The dosage regimen of claim 1 comprising administering about 275 mg to
20 about 325 mg of tramadol in a controlled release dosage form once-a-day for at least 7 days and optionally thereafter.
7. The dosage regimen of claim 6 wherein the tramadol is present in each oral dosage form in the form of tramadol hydrochloride.
8. The dosage regimen of claim 7 wherein each oral dosage form provides an *in*
25 *vitro* release of tramadol hydrochloride of about 24 hours or more.
9. A dosage regimen for administering tramadol to a patient comprising administering: about 100 mg of tramadol in a controlled release dosage form once-a-day on days 1 through 7; then about 200 mg of tramadol in a controlled release dosage form once-a-day on days 8 through 14; then about 300 mg of tramadol in a controlled release dosage
30 form once-a-day on day 15 and optionally thereafter.
10. The dosage regimen of claim 9 wherein the controlled release dosage forms are each oral dosage forms.
11. The dosage regimen of claim 10 wherein the tramadol is present in each oral dosage form in the form of tramadol hydrochloride.

12. The dosage regimen of claim 11 each oral dosage form provides *in vitro* release of tramadol hydrochloride for about 24 hours or longer.

13. The dosage regimen of claim 9 comprising administering about 300 mg of tramadol in a controlled release dosage form once-a-day on days 15 through 21 and optionally thereafter.

14. The dosage regimen of claim 13 wherein 100 mg of tramadol is administered on days 1 through 7; 200 mg of tramadol is administered on about days 8 through 14; and 300 mg of tramadol is administered on days 15 through 21 and optionally thereafter.

15. The dosage regimen method of claim 14 wherein the tramadol is present in each oral dosage form in the form of tramadol hydrochloride.

16. The dosage regimen method of claim 15 wherein each oral dosage form provides an *in vitro* release of tramadol hydrochloride of about 24 hours or more.

17. A dosage regimen for administering tramadol to a patient comprising administering: about 175 mg to about 225 mg of tramadol in a controlled release dosage form once-a-day for about 4 to about 10 days; then about 275 mg to about 325 mg of tramadol in a controlled release dosage form once-a-day for at least 1 day and optionally thereafter.

18. The dosage regimen of claim 17 wherein the controlled release dosage forms are each oral dosage forms.

19. The dosage regimen of claim 18 wherein the tramadol is present in each oral dosage form in the form of tramadol hydrochloride.

20. The dosage regimen of claim 20 wherein each oral dosage form provides an *in vitro* release of tramadol hydrochloride of about 24 hours or more.

21. The dosage regimen of claim 17 comprising administering about 275 mg to about 325 mg of tramadol in a controlled release dosage form once-a-day for at least 6 days and optionally thereafter.

22. A dosage regimen for administering tramadol to a patient comprising administering: about 200 mg of tramadol in a controlled release dosage form once-a-day for days 1 through 7; then about 300 mg of tramadol in a controlled release dosage form once-a-day for at least 1 day and optionally thereafter.

23. The dosage regimen of claim 22 wherein the controlled release dosage forms are each oral dosage forms.

24. The dosage regimen of claim 23 wherein the tramadol is present in each oral dosage form in the form of tramadol hydrochloride.

25. The dosage regimen of claim 24 wherein each oral dosage form provides an *in vitro* release of tramadol hydrochloride of about 24 hours or more.

26. The dosage regimen of claim 22 comprising administering about 300 mg of tramadol in a controlled release dosage form once-a-day for at least 7 days and optionally thereafter.

27. A kit for the administration of a dosage regimen of tramadol comprising: instructions to administer the following amounts of tramadol in controlled release oral dosage forms according to the following dosage regimen:

100 mg of tramadol once-a-day on days 1 through 7;

200 mg of tramadol once-a-day on about days 8 through 14; and

300 mg of tramadol once-a-day on about days 15 through 21,

and optionally thereafter; and

a sufficient quantity of controlled release oral dosage forms of tramadol to administer tramadol according to the dosage regimen.

28. The kit of claim 27 wherein each oral dosage form contains an amount of tramadol selected from the group consisting of 100 mg, 200 mg and 300 mg.

29. A kit for the administration of a dosage regimen of tramadol comprising: instructions to administer the following amounts of tramadol in controlled release oral dosage forms according to the following dosage regimen:

200 mg of tramadol once-a-day on days 1 through 7; and

300 mg of tramadol once-a-day on about days 8 through 14,

and optionally thereafter; and

a sufficient quantity of controlled release oral dosage forms of tramadol to administer tramadol according to the dosage regimen.

30. The kit of claim 29 wherein each oral dosage form contains an amount of tramadol selected from the group consisting of 100 mg, 200 mg and 300 mg.